REMARKS

Claims 59-131 are pending in this application. In the June 20, 2007 Office Action, the Examiner contended that claims 59-131 comprise six separate, patentably distinct inventions, namely:

- Group I (claims 59-78 and 88-91) directed to an oral dosage form of unmodified insulin,

- Group II (claims 79-87) directed to an oral dosage form of unmodified insulin with a specified delivery agent,

- Group III (claims 92-101 and 106-109) directed to a method of treating a human diabetic patient by administering an oral dosage form of unmodified insulin,

- Group IV (claims 102-105, 117, 118 and 131) directed to a method of treating a human diabetic patient by administering an oral dosage form of unmodified insulin with a specified delivery agent,

- Group V (claims 110-116 and 119-129) directed to a method of reducing the incidence of hyperinsulemia and cardiovascular disease associated with diabetes by administering an oral dosage form of unmodified insulin, and

- Group VI (claim 130) directed to method of attenuating processes resulting from the reaction to a mild injurious stimulus in multiple areas of the response to increases in mRNA during insulin treatment by administering an oral dosage form of unmodified insulin.

The Examiner stated that Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because oral dosages of unmodified insulin are known in the art (see Weiner et al., U.S. Patent Application Publication No. 2001/0056063, which allegedly discloses a solid oral dosage form of insulin for the treatment of Type I diabetes), such that the inventions lack unity retroactively. The Examiner required that Applicants elect one group of invention for prosecution in this application and identify the claims that are encompassed by the elected invention.

Applicants, **with traverse**, elect to prosecute Group II, namely claims 79-87, drawn to an oral dosage form of unmodified insulin with a specified delivery agent.

The election is made with traverse for the following reasons. Applicants do not agree that all of the claims of Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1.

Applicants argue that Groups II and IV relate to a single general inventive concept under PCT Rule 13.1, such that the claims of Group IV (claims 102-105, 117, 118 and 131), drawn to a method of treating a human diabetic patient by administering an oral dosage form of unmodified insulin with a specified delivery agent, should be examined together with the claims of Group II. A delivery agent that is specified in Group IV claims 102-105, 117, 118 and 131 is the same as a delivery agent that is specified in Group II claims 79-87, namely 4-[(4-chloro, 2-hydroxybenzoyl)amino]butanoic acid. Groups II and IV relate to a single general inventive concept under PCT Rule 13.1 because, in accordance with PCT Rule 13.2, Group II claims 79-87 and Group IV claims 102-105, 117, 118 and 131 both possess the same or corresponding special technical feature, namely an oral dosage form of unmodified insulin with a delivery agent such as 4-[(4-chloro, 2-hydroxybenzoyl)amino]butanoic acid or its use to treat human diabetic patients..

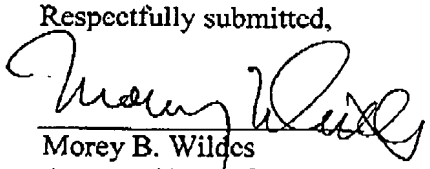
The Examiner cannot contend that the claims of Groups II and VI are related as product and process of use and that the product of Group II can be used in a process materially different from that of Group IV, such that restriction is required. In fact, the claims of Group II (through their dependency upon claim 59) require that the oral dosage form achieve a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient as compared to an untreated diabetic patient. Similarly, the claims of Group IV (through their dependency upon claim 92) require that the administration of the oral dosage form achieve a therapeutically effective reduction in blood glucose after oral administration to a human diabetic patient. There therefore can be no other process with which the oral dosage form of Group II can be used that is materially different from the process of Group IV.

Applicants have not withdrawn any non-elected claims at this time, pending approval by the Examiner, because Applicants may desire to make certain non-elected claims dependent upon elected claims. Applicants reserve all rights in the non-elected claims to file divisional and/or continuation patent applications at a later date.

If the Examiner has any questions or comments as to this response, the undersigned may be contacted at the address and telephone number below.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



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